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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93 N-0253]

Mark Perkal; Grant of Special Termination; Final Order Terminating Debarment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) granting special termination of the debarment of Mark Perkal, Israel. FDA bases this order on a finding that Dr. Perkal provided substantial assistance in the investigations or prosecutions of offenses relating to a matter under FDA's jurisdiction and that special termination of Dr. Perkal's debarment serves the interest of justice and does not threaten the integrity of the drug approval process.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register.)**

ADDRESSES: Comments should reference Docket No. 93 N-0253 and be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–204 1.

SUPPLEMENTARY INFORMATION:

In a **Federal Register** notice dated November 29, 1993 (58 FR 62676), Mark Perkal, the former Executive Vice President and Chief Scientific Officer of PharmaKinetics Laboratories, Inc., was permanently debarred from providing services in any capacity to a person with an approved or pending drug product application (21 U.S.C. 335a(c)(1)(B) and (a) and 21 U.S.C.

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321 (old)). The debarment was based on FDA's finding that Dr. Perkal was convicted of a felony under Federal law for conduct relating to the development or approval of any drug product, or otherwise relating to the regulation of a drug product (21 U.S.C. 335a(a)(2)). On April 14, 1995, Dr. Perkal applied for special termination of debarment under section 306(d)(4) of the act(21 U.S.C. 335a(d)(4)), as amended by the Generic Drug Enforcement Act (GDEA).

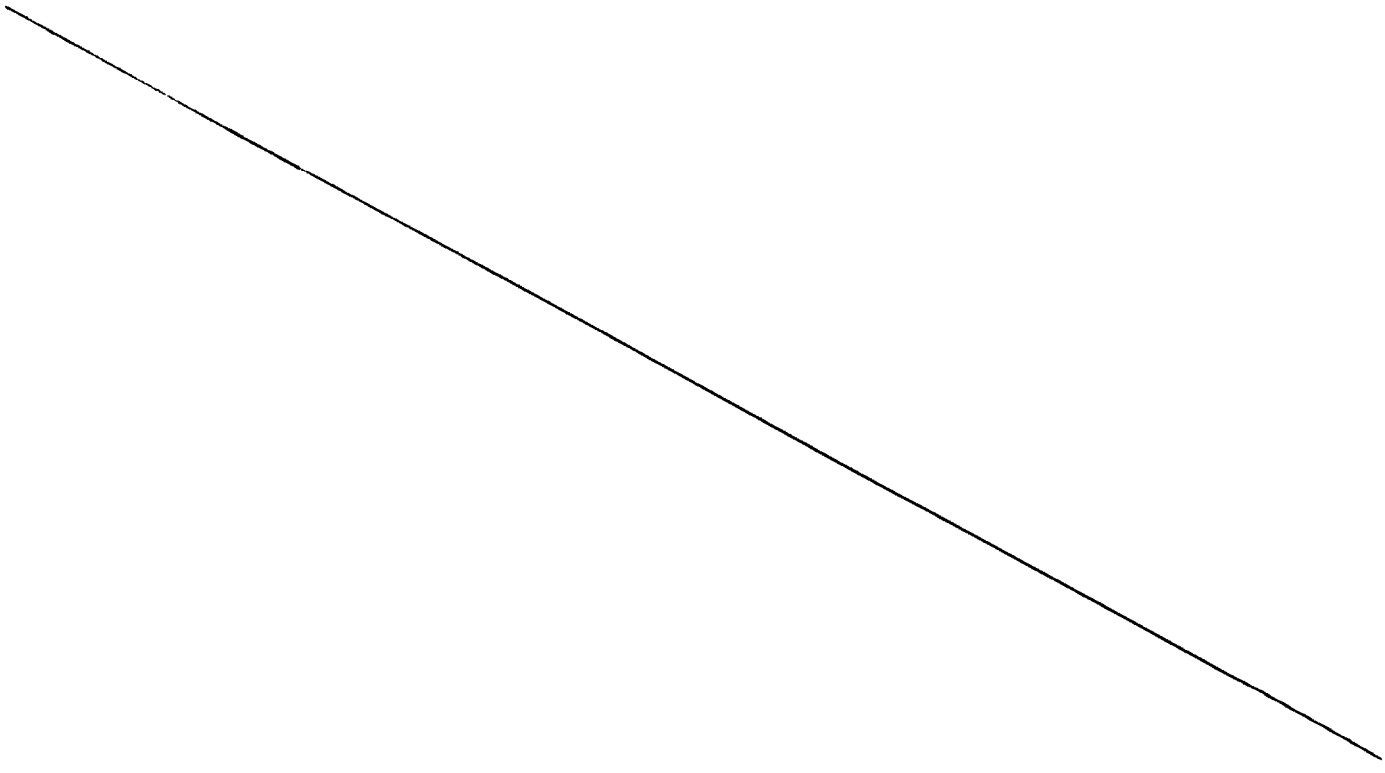
Under section 306(d)(4)(C) and (d)(4)(D) of the act, FDA may limit the period of debarment of a permanently debarred individual if the agency finds that: (1) The debarred individual has provided substantial assistance in the investigation or prosecution of offenses described in subsections (a) or (b) of section 306 of the act or relating to a matter under FDA's jurisdiction; (2) termination of the debarment serves the interest of justice; and (3) termination of the debarment does not threaten the integrity of the drug approval process. Special termination of debarment is discretionary with FDA.

FDA considers a determination by the Department of Justice concerning the substantial assistance of a debarred individual conclusive in most cases. Dr. Perkal cooperated with the Department of Justice investigations and prosecutions of others, as substantiated by the testimony of the Assistant U.S. Attorney at Dr. Perkal's sentencing. Accordingly, FDA finds that Dr. Perkal provided substantial assistance as required by section 306(d)(4)(C) of the act.

The additional requisite showings that termination of debarment serves the interest of justice and poses no threat to the integrity of the drug approval process are difficult standards to satisfy. In determining whether these have been met, the agency weighs the significance of all favorable and unfavorable factors in light of the remedial, public health-related purposes underlying debarment. Termination of debarment will not be granted unless, weighing all favorable and unfavorable information, there is a high level of assurance that the conduct that formed the basis for the debarment has not recurred and will not recur, and that the individual will not otherwise pose a threat to the integrity of the drug approval process.

The evidence presented to FDA in support of termination shows that Dr. Perkal was convicted for a first offense; that he has no prior or subsequent convictions for conduct described under the GDEA and has committed no other wrongful acts affecting the drug approval process; and that his character and scientific ability are highly regarded by his professional peers. The evidence presented supports the conclusion that the conduct upon which Dr. Perkal's debarment was based is unlikely to recur. For these reasons, the agency finds that termination of Dr. Perkal's debarment serves the interest of justice and will not pose a threat to the integrity of the drug approval process.

Under section 306(d)(4)(D) of the act, the period of debarment of an individual who qualifies for special termination may be limited to less than permanent but to no less than 1 year. Dr. Perkal's period of debarment has lasted more than 1 year. Accordingly, the Deputy Commissioner for Operations, under section 306(d)(4) of the act and under authority delegated to him (21 CFR 5.20), finds that Mark Perkal's application for special termination of debarment should be granted, and that the period of debarment should terminate immediately, thereby allowing him to provide services in any capacity to a person with an approved or pending drug product application. The Deputy Commissioner for Operations further finds that because the agency is granting Dr. Perkal's application, an informal hearing under section 306(d)(4)(C) of the act is unnecessary.



As a result of the foregoing findings, Dr. Mark Perkal's debarment is terminated effective (*insert date of publication in the* **Federal Register) (21** U.S.C. 335a(d)(4)(C) and (d)(4)(D)).

Dated: September 2, 1998

Michael A. Friedman
Deputy Commissioner for Operations

[FR **Dec. 98-????** Filed ??-??-98; 8:45 am]

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